

FEB 13 2004

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510(k) Premarket Notification
CONFIDENTIAL

APPENDIX A. 510(k) SUMMARY

A. Sponsor/Submitter: Abbott Vascular Devices
400 Saginaw Drive
Redwood City, CA 94063

B. Contact Person: Joanna Kuskowski
Regulatory Affairs Coordinator
Phone:(650) 474-3331
Fax:(650) 474-3020

Date of Submission: December 16, 2003

Device Trade Name: wavemaX™ Balloon-Expandable Transhepatic Biliary Stent System

Device Common Name: Biliary Stent and Delivery System

Device Classification: Class II

Regulation Number: 21 CFR 876.5010

Classification Name: Biliary Catheter and Accessories

Product Code: 78 FGE

Predicate Device: Cordis Palmaz Genesis Transhepatic Biliary Stent (K012590)
Abbott Vascular Devices Xpert™ Self-Expanding Transhepatic Biliary Stent System (K033537)

Intended Use: The wavemaX™ Balloon-Expandable Transhepatic Biliary Stent System is intended for use in the palliation of malignant neoplasms in the biliary tree.

Device Description: The wavemaX™ Balloon-Expandable Transhepatic Biliary Stent System is comprised of a balloon-expandable stent mounted on an over the wire (OTW) delivery system designed to deliver the stent to the biliary tree.

Summary of Substantial Equivalence: Abbott Vascular Devices has submitted information on indication for use, design and principle of operation, biocompatibility and performance characteristics to establish that wavemaX™ Balloon-Expandable Transhepatic Biliary Stent System is substantially equivalent to currently marketed predicate device.

The wavemaX™ Balloon-Expandable Transhepatic Biliary Stent System has the same intended use as the predicate device. Results of scientific testing have ensured that all materials are biocompatible, no new adverse effects were introduced and physical properties are appropriate for the intended use. Non-clinical testing was conducted.

In conclusion, the wavemaX™ Balloon-Expandable Transhepatic Biliary Stent System has been shown to be substantially equivalent to the Class II predicate upon which the device is based.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 13 2004

Ms. Joanna Kuskowski
Regulatory Affairs Coordinator
Abbott Vascular Devices
400 Saginaw Drive
Redwood City, California 94063

Re: K033909

Trade/Device Name: wavemaX™ Balloon-Expandable Transhepatic Biliary Stent System
Regulation Number: 21 CFR §876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: 78 FGE
Dated: December 16, 2003
Received: December 17, 2003

Dear Ms. Kuskowski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

The safety and effectiveness of this device for use in the vascular system have not been established.

Furthermore, the indication for biliary use must be prominently displayed in all labeling, including pouch, box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

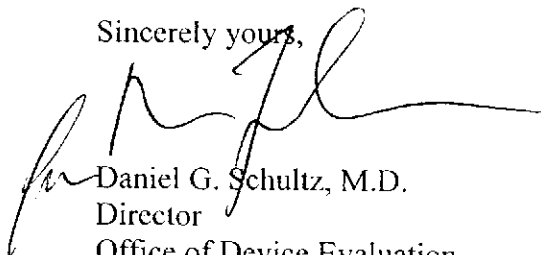
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4616. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International, and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Daniel G. Schultz", is written over the typed name and title.

Daniel G. Schultz, M.D.

Director

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

510(k) Number: K033909

Device Name: Abbott Vascular Devices wavemaX™ Balloon-Expandable Transhepatic Biliary Stent System


FDA's Statement of the Indications For Use for device:

The Abbott Vascular Devices wavemaX™ Balloon-Expandable Transhepatic Biliary Stent System is intended for use in the palliation of malignant neoplasms in the biliary tree.

Prescription Use ☒
 (Per 21 CFR 801.109)

OR

Over-the-Counter Use ☐


(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K033909